REMARKS

The specification has been amended to claim priority to provisional application number 60/144,084. The specification has also been amended to explicitly reference the sequence listing in computer readable form in the present application, and to remove embedded hyperlinks from all website addresses. No new matter enters by way of these amendments.

Claim 1 has been amended to reflect the elected SEQ ID NO: 2. Claims 8 through 13 have been added. Support for the foregoing claim amendments and new claims may be found throughout the specification, for example at page 11, lines 9-11, at page 22, line 14 through page 23, line 13, in the sequence listing, and in the original claims. No new matter enters by these amendments. Upon entry of the foregoing amendments, claims 1 and 8-13 are pending in the application.

1. Election/Restriction Requirement

Applicants acknowledge the finality of the restriction requirement but maintain their traversal. To facilitate prosecution, however, Applicants have removed the non-elected claims from the application.

Applicants further acknowledge the finality of the election requirement to a single nucleotide sequence, but maintain their traversal. Applicants submit that election of a single nucleotide sequence is improper and Applicants believe no serious burden would result by the search and examination of at least ten nucleotide sequences. The election of a single nucleic acid sequence contravenes the USPTO policy as set forth in the Manual of Patent Examining Procedure stating that "to further aid the biotechnology industry in protecting its intellectual property without creating an undue burden on the Office, the Commissioner has decided ... to permit a reasonable number of such nucleotide

sequences to be claimed in a single application." (M.P.E.P., 8th ed., rev. 1, February 2003, Section 803.04). The MPEP further provides that "[i]t has been determined that normally ten sequences constitute a reasonable number for examination purposes." (emphasis added) *Id.* While the Examiner requires that a single nucleotide sequence be selected, no reason has been provided for this deviation from articulated Patent Office policy.

Although Applicants disagree with the election requirement of a single nucleotide sequence, to facilitate prosecution the claims have been amended to reflect the elected SEQ ID NO: 2.

2. Sequence Listing

Applicants thank the Examiner for indicating that the computer-readable sequence listing was approved by SITC for matters of form.

3. Specification Objections

In the Office Action at page 3, the Examiner has objected to the specification because "it contains an embedded hyperlink and/or other form of browser-executable code." Applicants have amended the specification to remove the phrase "http://www" and embedded hyperlinks. Applicants' disclosure, as amended, contains no browser-executable code in the absence of embedded hyperlinks and/or other forms of browser-executable code. *See* M.P.E.P., § 608.01. Accordingly, Applicants respectfully request that the Examiner withdraw the objection.

4. Rejection of Claim 1 Under 35 U.S.C. §§ 101 and 112, First Paragraph

The Examiner has rejected claim 1 under 35 U.S.C. § 101, for allegedly lacking a patentable utility. Office Action at pages 4-6. Applicants respectfully disagree.

The Examiner acknowledges that the specification describes multiple utilities for the present invention, including "acquiring genes, identifying polymorphisms, determining plant traits, and DNA mapping." Office Action at page 5. However, the Examiner contends that none of these utilities are "specific and substantial." Applicants respectfully disagree with this assertion.

It is well-established that "when a properly claimed invention meets at least one stated objective, utility under section 101 is clearly shown." *Raytheon Co. v. Roper Corp.*, 724 F.2d 951, 958, 220 U.S.P.Q. 592, 298 (Fed. Cir. 1983). The present specification describes many objectives that are met by the present invention. In addition to the utilities described by the Examiner (quoted above), the claimed nucleic acid molecules are useful for isolating a variety of agronomically significant genes, acquiring molecular markers, promoters, transcriptional regulatory elements, etc. *See, e.g.*, page 38, *et. seq.*, under the heading "Uses of the Agents of the Invention." The claimed nucleic acid molecules also find use in the reduction of endogenous protein expression through cosuppression and antisense applications. *See, e.g.* page 95, line 22 through page 98, line 14.

Many of these uses are directly analogous to the use of a microscope. An important utility of a microscope resides in its use to identify and characterize the structure of biological tissues in a sample, cell or organism. Significantly, the utility of the microscope under 35 U.S.C. § 101 is not compromised by its use as a tool in this manner. Many of the presently disclosed utilities are directly analogous to the utilities of a microscope, *i.e.*, the claimed nucleic acid molecules may be used to identify and characterize other nucleic acid molecules within a sample, cell or organism. Such utility is indistinguishable from the legally sufficient utility of a microscope. Thus, the presently disclosed nucleic acid molecules possess the requisite utility under 35 U.S.C. § 101.

In the Office Action, the Examiner provides no evidence challenging the disclosed utilities for the presently claimed nucleic acid molecules. Rather the Examiner attempts to undermine the existing utilities by stating that "the disclosed uses are generally applicable to broad classes of this subject matter" and further asserts that the disclosed utilities are "neither substantial nor specific due to being generic in nature and applicable to a myriad of such compounds." Office Action at pages 4-6. In short, the Examiner suggests that the asserted utilities are legally insufficient simply because other molecules can be used for the same purpose. This position is wrong as a matter of law – there is no requirement of exclusive utility in the patent law. *See Carl Zeiss Stifung v. Renishaw PLC*, 945 F.2d 1173, 1180, 20 U.S.P.Q.2d 1094, 1100 (Fed. Cir. 1991) ("An invention need not be the best or the only way to accomplish a certain result…").

Such an argument implies that a new golf club has no legal utility because other golf clubs can be used for the same purpose, *i.e.,* hitting golf balls. Such a result is not only untenable, but requires reading "into the patent laws limitations and conditions which the legislature has not expressed," a practice condemned by the Supreme Court. *See Diamond v. Chakrabarty*, 447 U.S. 303, 308, 306 U.S.P.Q. 193, 196 (1980), *quoting United States v. Dubilier Condenser Corp.,* 289 U.S. 178, 199, 17 U.S.P.Q. 154, 163 (1933). Thus, it must be the case that a utility, generic to a broad class of molecules, does not compromise the specific utility of an individual member of that class.

As noted above, the claimed nucleic acid molecules have many utilities. Some of these utilities may be common to a broader class of molecules. For instance, nucleic acid sequences may generally be used to identify and locate related sequences. However, when used in this manner, the result is not generic. Rather, the claimed nucleic acid molecules will identify a ***unique*** subset of related sequences. This subset of related sequences is specific to the claimed sequences and cannot be identified by any generic nucleic acid molecule. For example, a random nucleic acid molecule would not provide

this specific utility. Referring again to the golf club analogy, the club is still generically hitting a golf ball, but is uniquely designed to hit a ball in a manner that is distinct from other clubs. Once again, Applicants assert that the claimed nucleic acid molecules exhibit the requisite utility under 35 U.S.C. § 101.

The Examiner also argues that the claimed nucleic acid molecules lack utility apparently because "[n]o open reading frame, start/stop codons, or encoded protein is identified in the specification for SEQ ID NO: 2." Office Action at pages 4-5. Applicants respectfully submit that the skilled artisan would be able to ascertain these elements based on Applicants' disclosure (*see, e.g.,* specification at page 101, line 14 through page 102, line 4 and the sequence listing) and tools available to practitioners in the art, *e.g.,* BLASTX. Moreover, the specification discloses that the nucleic acid molecules of the present invention encode soybean proteins or fragments thereof. Therefore, a complete ORF or start codon is not necessary for every claimed nucleic acid molecule. Furthermore, a complete ORF is not necessary to use the claimed nucleic acid molecules for the disclosed utilities, for example, as probes, to detect the presence or absence of polymorphisms, and in cosuppression/antisense applications.

The Examiner also states that the credibility of the presently asserted utilities has not been assessed. Office Action at page 6. Credibility is precisely the issue that the courts have emphasized in evaluating the adequacy of an asserted utility. Utility is determined "by reference to, and a factual analysis of, the disclosure of the application." *In re Ziegler*, 992 F.2d 1197, 1201, 26 U.S.P.Q.2d 1600, 1603 (Fed. Cir. 1993), *quoting Cross v. Iizuka*, 752 F.2d 1040, 1044, 224 U.S.P.Q. 739, 742 (Fed. Cir. 1985). The Examiner "has the initial burden of challenging a presumptively correct assertion of utility in the disclosure." *In re Brana*, 51 F.3d 1560, 1567, 34 U.S.P.Q.2d 1436, 1441 (Fed. Cir. 1995). The utilities asserted in the specification must be accepted as factually sound unless the Patent Office cites information that undermines the credibility of the

assertion. *Id.* The Examiner "must do more than merely question – [he] must set forth factual reasons which would lead one skilled in the art to question the objective truth of the statement of operability." *In re Gaubert*, 524 F.2d 1222, 1225-26, 187 U.S.P.Q. 664, 666 (C.C.P.A. 1975) (emphasis in original); M.P.E.P. § 706.03(a)(1) ("Office personnel are reminded that they must treat as true a statement of fact made by an applicant in relation to an asserted utility, unless countervailing evidence can be provided..."). Here the Examiner has not even attempted to meet this burden. Thus, the Examiner's admission that the credibility of the disclosed utilities is not challenged is tantamount to an admission that no proper rejection has been made.

In view of the above, Applicants contend that the claimed nucleic acid molecules are supported by credible, specific and substantial utilities disclosed in the specification. Moreover, the Examiner has failed to raise any credible evidence challenging the presently asserted utilities. Consequently, the rejection of claim 1 is improper. Reconsideration and withdrawal of this rejection are respectfully requested.

5. Rejection Under 35 U.S.C. § 112, 1st Paragraph: Enablement

The Examiner has rejected claim 1 as not being enabled by the specification, because the claimed invention allegedly lacks utility. Office Action at page 6. Applicants respectfully disagree and assert that the rejection has been overcome by the foregoing arguments regarding utility. Thus, the enablement rejection under 35 U.S.C. § 112, first paragraph is improper. Reconsideration and withdrawal are respectfully requested.

6. Rejection Under 35 U.S.C. §112, 1st Paragraph: Written Description

The Examiner has rejected claim 1 under 35 U.S.C. § 112, first paragraph, for allegedly lacking an adequate written description. Office Action at pages 7-8. Applicants respectfully disagree.

Although the Examiner acknowledges that the specification discloses SEQ ID NO: 2, claim 1 allegedly fails to meet the written description requirement because the "specification provides insufficient written description to support the genus encompassed by the claim." Office Action at page 7. Applicants respectfully disagree with this contention.

An adequate written description of a genus of nucleic acids, as recited in claim 1 may be achieved by either "a recitation of a representative number of [nucleic acid molecules], defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus." *Regents of the University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568-69 (Fed. Cir. 1997). The feature relied upon to describe the claimed genus must be capable of distinguishing members of the claimed genus from non-members. *Id.*

The purpose of the written description requirement is to ensure that the inventors had possession of the claimed subject matter, *i.e.*, to ensure that the inventors actually invented what is claimed. *Gentry Gallery Inc. v. Berkline Corp.*, 134 F.3d 1473, 1479, 45 U.S.P.Q.2d 1498, 1503 (Fed. Cir. 1998); *Lockwood v. American Airlines*, 107 F.3d 1565, 1572, 41 U.S.P.Q.2d 1961, 1966 (Fed. Cir. 1997); *In re Alton*, 76 F.3d 1168, 1172, 37 U.S.P.Q.2d 1578, 1581 (Fed. Cir. 1996). In accordance with this purpose, Applicants need not "describe," in the sense of Section 112, all things that are encompassed by the claims. To contend otherwise would contradict established jurisprudence, which teaches that a patent may be infringed by technology developed after a patent issues. *United States Steel Corp. v. Phillips Petroleum Co.*, 865 F.2d 1247, 1251, 9 U.S.P.Q.2d 1461,

1464 (Fed. Cir. 1989). A related, and equally well-established principle of patent law is that claims "may be broader than the specific embodiment disclosed in a specification." *Ralston Purina Co. v. Far-mor-Co*, 772 F.2d 1570, 1575, 227 U.S.P.Q. 177, 179 (Fed. Cir. 1985), *quoting In re Rasmussen*, 650 F.2d 1212, 1215, 211 U.S.P.Q. 323, 326 (C.C.P.A. 1981). Thus, in order for Applicants to describe each and every molecule encompassed by the claims, it is not required that every aspect of those nucleic acid molecules (*e.g.*, an open reading frame) be disclosed. *In re Alton,* 76 F.3d 1168, 1175 (Fed. Cir. 1996) (if a person of ordinary skill in the art would have understood the inventor to have been in possession of the claimed invention at the time of filing even if every nuance of the claims is not explicitly described in the specification).

The Examiner further contends that "the skilled artisan cannot envision the detailed chemical structure of the encompassed polynucleotides and/or proteins." Office Action at page 8. According to the Examiner, proper written description support for a claim directed to a nucleic acid sequence requires nothing less than the actual disclosure of every sequence encompassed by that claim. In support of this proposition, the Examiner relies on *Fiers v. Revel*, 25 U.S.P.Q.2d 1601, 1606 (Fed. Cir. 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 U.S.P.Q.2d 1016 (Fed. Cir. 1991). Applicants respectfully disagree. Unlike the sequences of the claims in *Amgen*, the sequences of the claims of the present invention could be ascertained by one of skill in the art. Moreover, the Amgen Court stated "we do not intend to imply that generic claims to genetic sequences cannot be valid where they are of a scope appropriate to the invention disclosed by an applicant." Amgen, 18 U.S.P.Q.2d 1016, 1027 (Fed. Cir. 1991). Thus, in the present case, unlike the appellant in *Fiers*, Applicants have indeed provided a chemical structure for the claimed nucleic acid molecules themselves, *i.e.*, SEQ ID NO: 2.

It is well-settled law that each nucleic acid molecule within a claimed genus does not need to be described by its complete structure. The Federal Circuit has elucidated a test for written description wherein a genus of nucleic acids may be described by a structural feature that distinguishes members of the claimed genus from non-members of the claimed genus. *Regents of the University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568-69, 43 U.S.P.Q.2d 1398, 1406 (Fed. Cir. 1997). In contrast to the mere name "cDNA" provided in *Eli Lilly*, Applicants have provided a detailed chemical structure by way of the claimed SEQ ID NO: 2. Applicants have therefore satisfied the *Eli Lilly* test for written description.

Applicants have provided a detailed chemical structure, *i.e.*, the nucleic acid sequence of SEQ ID NO: 2. Nucleic acid molecules falling within the scope of claim 1 are readily identifiable – they comprise a nucleic acid molecule having the nucleic acid sequence of SEQ ID NO: 2. The fact that the nucleic acid molecules may comprise additional sequences or variations is beside the point. Such modifications are readily envisioned by one of ordinary skill in the art and disclosed through the present specification. Thus, there is no deficiency in the written description support for claim 1. Therefore, claim 1 satisfies the written description requirement of 35 U.S.C. § 112, first paragraph. Reconsideration and withdrawal of this rejection are respectfully requested.

Conclusion

In view of the foregoing amendments and remarks, it is respectfully submitted that the present application is now in condition for allowance, and notice of such is respectfully requested. The Examiner is encouraged to contact the undersigned should any additional information be necessary for allowance.

Respectfully submitted,

Thomas E. Holsten (Reg. Agent No. 46,098)
Holly Logue Prutz (Reg. Atty. No. 47,755)

Date: October 8, 2003

MONSANTO COMPANY
800 N. Lindbergh Blvd.
Mailzone N2NB
St. Louis, MO 63167
(314) 694-3602 telephone
(314) 694-1671 facsimile

SPECIFICATION AMENDMENTS

Please **add** the following paragraphs on page 1 line 5, following the title:

CROSS REFERENCE TO RELATED APPLICATIONS

This application claims priority under 35 U.S.C. § 119(e) of U.S. Provisional Application No. 60/144,084, filed July 16, 1999.

INCORPORATION OF SEQUENCE LISTING

A copy of the Sequence Listing in computer readable form containing the file named JULSOYREG.rpt, which is 52,867,083 bytes in size (measured in MS-DOS) and created on January 21, 2003, is herein incorporated by reference.

Please **amend** the specification by replacing the paragraph on page 6, lines 7-16 with the following amended paragraph:

Similarity analysis includes database search and alignment. Examples of public databases include the DNA Database of Japan (DDBJ)(accessible on the web at ~~http://www.~~ddbj.nig.ac.jp/); Genebank (accessible on the web at ~~http://www.~~ncbi.nlm.nih.gov/web/Genbank/Index.htlm); and the European Molecular Biology Laboratory Nucleic Acid Sequence Database (EMBL) (accessible on the web at ~~http://www.~~ebi.ac.uk/ebi_docs/embl_db.html). A number of different search algorithms have been developed, one example of which are the suite of programs referred to as BLAST programs. There are five implementations of BLAST, three designed for nucleotide sequence queries (BLASTN, BLASTX, and TBLASTX) and two designed for protein sequence queries (BLASTP and TBLASTN) (Coulson, *Trends in Biotechnology, 12:* 76-80 (1994); Birren, *et al., Genome Analysis, 1:* 543-559 (1997)).

CLAIM AMENDMENTS

Please amend claim 1 as follows.

Please cancel non-elected claims 2-7.

Please add claims 8-13.

1. (Currently Amended) A substantially purified nucleic acid molecule that encodes a soybean protein or fragment thereof comprising a nucleic acid sequence ~~selected from the group consisting~~ of SEQ ID NO: ~~1 through SEQ ID NO: 55540~~ 2.

Claims 2-7 (canceled)

8. (New) A substantially purified nucleic acid molecule comprising a nucleic acid sequence of SEQ ID NO: 2 or complement thereof.

9. (New) A substantially purified nucleic acid molecule consisting of a nucleic acid sequence of SEQ ID NO: 2 or complement thereof.

10. (New) A substantially purified nucleic acid molecule comprising a nucleic acid sequence having between 100% and 90% sequence identity with a nucleic acid sequence of SEQ ID NO: 2 or complement thereof.

11. (New) The substantially purified nucleic acid molecule of claim 10, wherein said nucleic acid molecule comprises a nucleic acid sequence having between 100% and 95% sequence identity with a nucleic acid sequence of SEQ ID NO: 2 or complement thereof.

12. (New) The substantially purified nucleic acid molecule of claim 11, wherein said nucleic acid molecule comprises a nucleic acid sequence having between 100% and 98% sequence identity with a nucleic acid sequence of SEQ ID NO: 2 or complement thereof.

13. (New) The substantially purified nucleic acid molecule of claim 12, wherein said nucleic acid molecule comprises a nucleic acid sequence having between 100% and 99% sequence identity with a nucleic acid sequence of SEQ ID NO: 2 or complement thereof.